FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

November 12, 2020

Kyle Crawford, Esq.
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Re: Subpoena issued to Food and Drug Administration in *In re: National Prescription Opiate Litigation*, Civil Action No. 1:17-md-02804-DAP

Dear Mr. Crawford:

This letter responds to your April 7, 2020 letter to Dr. Stephen Hahn, the Commissioner of Food and Drugs (Commissioner), sent pursuant to Title 21, Code of Federal Regulations, section 20.1 (*Touhy* letter). The *Touhy* letter was sent in support of the Pharmacy Defendants'[1] subpoena for testimony of a United States Food and Drug Administration (FDA or agency) employee in *In re National Prescription Opiate Litigation,* MDL No. 2804, Track One-B Cases (N.D. Ohio).

Requests for testimony of Department of Health and Human Services (HHS) employees that pertain to any function of FDA are governed by Title 21, Code of Federal Regulations, section 20.1 (21 C.F.R. § 20.1). This regulation prohibits HHS employees from providing testimony pertaining to any function of the FDA or with respect to any information acquired in the discharge of their official duties at FDA except with the express authorization of the Commissioner or an employee designated by him to act on his behalf. As Acting Director, Office of Strategic Planning and Operational Policy, I have been delegated the authority by the Commissioner to review these requests.

Section 20.1 provides that a request for testimony may be granted upon a determination that the testimony requested is both in the public health interest and furthers the objectives of the Federal Food, Drug, and Cosmetic Act (FDCA) and the agency. Because of limited resources and the vast number of requests the agency receives for personnel to testify in litigation to which FDA is not a party, FDA may, in its discretion, disapprove a request for testimony even when these prerequisites have been met. FDA must deny requests that are duplicative, unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. Accordingly, the agency must carefully assess requests for testimony made pursuant to section 20.1.

After considering the merits of your request, FDA hereby authorizes Theresa Toigo, Associate Director, Drug Safety Operations, Center for Drug Evaluation and Research (CDER), as a fact witness to provide four consecutive hours of deposition testimony regarding:

[1] The *Touhy* letter defines the term "Pharmacy Defendants" to mean CVS Rx Services, Inc., CVS Indiana, L.L.C., CVS Pharmacy, Inc., Ohio CVS Store L.L.C., Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center, Rite Aid of Ohio, Inc., Rite Aid Hdqtrs. Corp., Walgreen Co., Walgreen Eastern Co., HBC Service Company (an unincorporated operating division of Giant Eagle, Inc.), Discount Drug Mart, and Wal-Mart, Inc.

U.S. Food & Drug Administration
12420 Parklawn Dr.
Rockville, MD 20857
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EXHIBIT 20
DEF-00198292

DEF-MDL-12071.00001

DEF-MDL-12071

- The roles and responsibilities of FDA and its organizational structure;
- FDA's role, responsibility, and processes for approving prescription drugs;
- FDA's role, responsibility, and processes for monitoring approved drugs;
- FDA's approval and monitoring of opioids, benzodiazepines, and muscle relaxers.

The witness is not authorized to disclose information that FDA is prohibited from disclosing by law, including trade secrets or confidential commercial or financial information held by third-party companies, individuals, or entities. *See* 18 U.S.C. § 1905 (both); 21 U.S.C. § 331(j) (trade secrets obtained under certain FDCA provisions). Further, FDA retains the right to assert any applicable privilege that an attorney representing the agency determines to be appropriate. The witness is not authorized to disclose any information over which FDA has asserted a privilege.

Please note that the FDA's Office of Chief Counsel has assigned Jennifer Argabright (240-402-0353) to assist with the preparation of Ms. Toigo's testimony.

Sincerely,

Marla Hendriksson -S

Digitally signed by Marla Hendriksson -S
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Marla Hendriksson
Acting Director
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs
U. S. Food and Drug Administration

bcc:

(chron, r/f, L(DiPaola)Kisner
OCC (Jennifer Argabright)
CDER (David Joy, Terry Toigo)